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K051052

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510(K) SUMMARY

Galil Medical LTD.

SeedNet System

Applicant's Name:

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Shaar Yokneam
Yokneam Industrial Park 20692
ISRAEL
Tel: 972-4-9591080
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Contact Person:

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VP Regulatory Affairs
Galil Medical Ltd.
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sarit@galil-medical.co.il

Trade Name: SeedNet/SeedNetGold System, CryoThera System, Cryo-Hit System

Classification: Cryosurgical Unit
Common/Usual Name: Cryosurgical unit with argon-cooled probes
Product Code: GEH
Regulation No.: 878.4350
Class: II; FDA has not specifically classified cryosurgical units with argon cooled cryoprobes as class II devices under 21 C.F.R. § 878.4350. However, FDA has cleared Galil Medical SeedNet™ and SeedNetGold™, which are cryosurgical units with argon-cooled Cryoprobes, as Class II devices (K031117, K003065, K010991, K011950, and K021261). Therefore, cryosurgical units with argon-cooled probes are Class II medical devices.

Predicate Devices:
Galil's SeedNet™ System and SeedNetGold™ System and Galil's Cryo-Hit™ System.

Intended Use:
The SeedNet System is intended for cryogenic destruction of tissue during surgical procedures. The SeedNet System is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

The SeedNet System has the following specific indications:

- Urology (ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia "BPH")
- Oncology (ablation of cancerous or malignant tissue and benign tumors, and palliative intervention)
- Dermatology (ablation or freezing of skin cancers and other cutaneous disorders.
  Destruction of warts or lesions, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas small hemanglomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratoses, cavernous hemanglomas, perianal condylomata, and palliation of tumors of the skin)
- Gynecology (ablation of malignant neoplasia or benign dysplasia of the female genitalia)
- General surgery (palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions.)
- ENT (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth).
- Thoracic surgery (ablation of arrhythmic cardiac tissue cancerous lesions)

- Proctology (ablation of benign or malignant growths of the anus or rectum, and hemorrhoids)

The SeedNet System may be used with a magnetic resonance imaging (MRI) device or an ultrasound device to provide real-time visualization of the cryosurgical procedure.

Performance Data & Substantial Equivalence:
The modified SeedNet System is substantially equivalent in all aspects, e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the commercially available SeedNet System. The principle changes between the devices include:

1. Addition of the cryoneedles and cryoprobes that are different sizes, shapes, or made of different materials
2. The MRI compatible SeedNet System was modified to include a remote MRI Compatible Mobile Distribution Panel (MDP)

3. Addition of functional features to the software that halt the operation of the system and indicate the user when no signal is detected from specific temperature sensors or thermocouples.

4. Inclusion of New General Use Template for use with the IceRod™ Cryoneedles

5. Provision of IceRod™ Prostate and Renal Kits.

6. Addition of the trade name CryoThera in addition to Cryo-Hit and SeedNet/SeedNetGold.

The modified SeedNet System and its modified accessories were subjected to a comprehensive testing process as part of the design verification process. This included electrical, mechanical and biocompatibility testing. The modified SeedNet System does not raise any new safety and/or effectiveness issues. Thus, the modified SeedNet System is substantially equivalent to the cleared SeedNet System (the SeedNet™; the SeedNetGold™ and the Cryo-Hit™).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2005

Galil Medical Ltd.
C/o Mr. Jonathan S. Kahan
Hogan and Hartson
555 13th Street, N.W.
Washington, District of Columbia 20009

Re: K051052
Trade/Device Name: SeedNet System (SeedNet/SeedNetGold System, CyroThera System, Cyro-Hit System)
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: April 19, 2005
Received: April 25, 2005

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051052

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INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: SeedNet System (SeedNet/SeedNetGold System, CryoThera System, Cryo- Hit System)

Indications for Use:

The SeedNet System is intended for cryogenic destruction of tissue during surgical procedures.

It is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

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- ENT (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth).
- Thoracic surgery (ablation of arrhythmic cardiac tissue and cancerous lesions,)
- Proctology (ablation of benign or malignant growths of the anus or rectum and hemorrhoids)

The SeedNet System may be used with a magnetic resonance imaging (MRI) device or an ultrasound device to provide real-time visualization of the cryosurgical procedure.

Prescription Use __x__ AND/OR (Part 21 C.F.R. 801 Subpart D)

Over-The-Counter Use _____ (PART 21 C.F.R. 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Reproductive
Neurological

K051052 9-8